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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,692	10/31/2005	Sabaratnam Sabanathan	37529-501N01US (101)	7840

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EXAMINER	
SHOME, ARUNDIPTA	

ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/762,692	SABANATHAN ET AL.	
	Examiner	Art Unit	
	ARUNDIPTA SHOME	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 27-50 are pending. This action is in response to the amendment filed 12-04-2008.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 27-32, 36-40, 42, 43, 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terstein (US Patent 5,499,995) in view of Ponn et al. (Treatment of peripheral bronchopleural fistulas with endobronchial occlusion coils. Annals of Thoracic Surgery, 1993 December; 56(6): 1343-7).

Regarding Claim 27, Terstein discloses a blocking element (the closure device of Fig. 13). A seal is formed with this blocking element (col. 2, line 64) so that air is prohibited from flowing past the blocking element in an exhalation direction and an inhalation direction. The blocking element is then released in the passageway (col. 4, lines 45-55).

Terstein does not disclose using the blocking element to close a bronchial passageway. Ponn et al. teaches a method of sealing shut a bronchial passageway with a blocking element (plugging bronchopleural fistulas with occlusion coils, see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the Terstein device to close a bronchial passageway using the method taught by Ponn because the Terstein device has embedding anchors (col. 3, lines 20-30) which better allows the device to be permanently embedded, as required by the method of Ponn (see abstract).

Since Ponn teaches inserting a blocking element device in a bronchial passageway, the combination of Terstein and Ponn will include inserting a blocking element in a bronchial passageway.

Regarding Claim 28, the blocking element is inserted in the bronchial passageway in a compressed state and expands into engagement with a passageway (see Terstein Figs. 1 and 2).

Regarding Claim 29, the blocking element expands into sealing engagement with the bronchial passageway to form an air tight seal between the blocking element and a wall of the bronchial passageway (col. 4, lines 45-55).

Regarding Claim 30, the blocking element comprises a securing element (frame 40) that is expandable to a shape suitable for engaging a wall of the bronchial passageway (col. 6, lines 50-55).

Regarding Claim 31, the blocking element is inserted in a compressed state and expands into engagement with the wall of the passageway (col.6, lines 50-55).

Regarding Claims 32 and 43, the blocking element comprises a cylindrical plug of biocomaptible material (balloon 46 is in the form of a plug when inflated and inherently biocompatible).

Regarding Claim 34, the securing element is a stent (see col. 3, lines 5-15).

Regarding Claims 35 and 46, the securing element comprises a memory metal (nitinol, see col. 3, lines 5-15).

Regarding Claims 36 and 47, the blocking element comprises a balloon 46.

Regarding Claim 37, Terstein discloses inserting a delivery tube into the passageway (guidewire 20), the delivery tube is loaded with the blocking element device. The delivery tube is

guided to a location within the bronchial passageway prior to releasing the blocking element device (col. 4, lines 35-45).

Regarding Claim 38, the blocking element device is released by pushing the blocking element out of a delivery tube (guidewire 20).

Regarding Claim 39, Terstein does not disclose providing a second blocking element. Ponn teaches that multiple blocking elements can be used to close a fistula. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a second blocking element as taught by Ponn in order to close a fistula if one blocking element cannot fully close the fistula (Ponn, page 1, col. 2 paragraph 2).

The second blocking element would be a copy of the Terstein device, and would thus block airflow in exhalation and inhalation directions, and would b released in the bronchial passageway.

Regarding Claim 40, the combination of Terstein and Ponn noted with respect to claim 27 is a method for treating lung disease.

Regarding Claim 42, Terstein discloses an apparatus for blocking air flow through a passageway. A securing element comprising a self expanding stent (frame 40) that engages a wall of a passageway to secure the apparatus therein is disclosed. The securing element maintains the apparatus in a fixed position in the passageway (col. 6, lines 57-60). A blocking element (balloon 46) is attached to the securing element and blocks airflow in the inhalation and exhalation directions.

Regarding Claim 48, Terstein does not disclose the exact dimensions of the blocking element. However, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the device to have the claimed dimensions. (The Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See *In re Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984)).

Regarding Claim 49, the combination of Terstein and Ponn noted with respect to claim 27 teaches the claimed limitations.

Regarding Claim 50, the stent 40 is a self expanding stent (col. 3, lines 5-15).

3. Claims 33 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terstein and Ponn as applied to claim 27 above, further in view of Carlisle (US Patent 5,658,330).

Regarding Claims 33 and 44, Terstein uses a balloon material for the plug (col. 4, lines 21-25). Terstein does not disclose using resiliently deformable closed cell foamed plastics material for the plug. Carlisle et al teaches using deformable closed cell silicone foam as a biocompatible material in a medical device implant (col. 3, lines 50-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Terstein's balloon material with a silicone closed cell foam as taught by Carlisle since silicone was well known in the art at the time the invention was made as a biocompatible substance, and substitution of one material for another would yield comparable performance.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terstein and Ponn as applied to claim 40 above, further in view of Lefrak et al. (Recent advances in surgery for emphysema, Annual Review of Medicine 1997;48:387-98).

Regarding Claim 41, Terstein does not disclose using the disclosed device to treat emphysema. Lefrak teaches that volume reduction surgery that removes volume occupying emphysematous lung is an effective treatment method for emphysema. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Terstein to treat emphysema in order to plug nonfunctioning emphysematous lung tissue and improve elastic recoil, as taught by Lefrak, so that a non-surgical option is available to reduce lung volume (abstract).

Response to Arguments

4. Applicant's arguments with respect to claims 27-50 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Ritchart (US Patent 4,994,069) discloses a vaso-occlusion coil for blocking vessels in a patient.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is (571)270-5539. The examiner can normally be reached on Monday through Friday 8:30am to 6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771